

**MDCH Comments and Recommendations for CON Standards Scheduled for 2008 Review  
Presented to CON Commission January 24, 2008**

| <b>CARDIAC CATHETERIZATION (CC) SERVICES</b>  |   |  |  |
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| <b>All Identified Issues</b>  | <b>Issues Recommended as Requiring Review</b> | <b>Recommended Course of Action to Review Issues</b> | <b>Other/Comments</b>  |
| 1. Continued regulation of CC Services under CON?   | Yes   | Next scheduled review to be done in 2011.            | Please see the note below.   |
| 2. Neither the Heart Rhythm Society, nor the American College of Cardiology have policies in place prohibiting qualified electrophysiologists from performing catheter-based radiofrequency ablations at facilities without on-site cardiac surgery. Given this, recommends reconsideration of this policy. | No  | None<br>(This issue was reviewed in 2007)            | Ablation remains in the Therapeutic category, thus must be done at facility that can do emergent open heart surgery in the event of a burn through to the esophagus or one of the great vessels in the chest. Although this risk is small, especially in a very well trained electrophysiologist, not all electrophysiologists are trained to perform ablation.                        |
| 3. Recommends seeing amended language that allows for non-complex ablations to be performed at hospitals without open heart surgery.  | No  | None<br>(This issue was reviewed in 2007)            | The committee did not undertake a discussion to rate "non-complex" versus "complex" in the context of facility ability to perform an ablation procedure at a non-Open Heart surgery site. The weight scores were calculated based upon the time and resources required to perform the particular procedure because of changes in technology and not on how "safe" they were to perform |

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|  |  |  | <p>at non-Open Heart facilities. At this point in time, the recommendation is to keep the standard as it is for ablation therapeutic procedure (with the exception of the weighting changes) until such time that the technology advances or that all electrophysiologists are trained to perform ablation procedures. An EP procedure is a diagnostic procedure that carries little risk to the patient. All electrophysiologists are trained to perform EP procedures. Placing a pacemaker or ICD, which should be based upon diagnostic EP is reasonable and carries minimal risk to the patient. This was thoroughly discussed and was felt to be safe to perform in the absence of an Open Heart Program because of the minimal likelihood of complications requiring Open Heart support.</p> |
| <p><b>Recommendation: The Department recommends that the Commission review the CC Standards in 2011 when they are again scheduled for review. The currently approved standards have yet to be implemented, and then must have an opportunity to be evaluated before any new revisions are made to the standards.</b></p> |  |  |  |

Note: Cardiac Catheterization (CC) Services Standards Scheduled for review in 2008 should continue to be regulated. These Standards were originally due for review in 2005. An issue paper on 'Cardiac Catheterization and Open Heart Surgeries Volume Requirements' was submitted to the Commission in June 2005 and a full review by the CCSAC was able to be completed in 2007. In January 2007, the CON Commission appointed the CC Standards Advisory Committee (CCSAC) to review the existing standards based upon the CON principles of cost, quality and access. The charge to the CCSAC also included the task of reviewing new and emerging technology related to the cardiac catheterization. The SAC extensively deliberated a number of issues and made recommendations to the CON Commission in December 2007. The CON Commission accepted the SAC recommendations and final language is currently being reviewed by the Joint Legislative Committee and the Governor for their approval.